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10/593,259	07/26/2007	Remo Kranich	014.0005-US00	6454
92049 7590 98/06/2010 J.A. Lindeman & Co. PLLC 3190 Fairview Park Drive			EXAMINER	
			CORNET, JEAN P	
Suite 480 Falls Church,	VA 22042		ART UNIT	PAPER NUMBER
			1628	
			NOTIFICATION DATE	DELIVERY MODE
			08/06/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Application No. Applicant(s) 10/593,259 KRANICH ET AL. Office Action Summary Examiner Art Unit JEAN CORNET 1628 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status

1) Responsive to communication(s) filed on 10 May 2010. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 11-16 is/are pending in the application. 4a) Of the above claim(s) 14-16 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 11-13 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application. Information Disclosure Statement(s) (FTO/SB/08) 6) Other: Paper No(s)/Mail Date U.S. Patent and Trademark Office Office Action Summary Part of Paper No./Mail Date 20100724 Application/Control Number: 10/593,259 Page 2

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

 A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/10/2010 has been entered.

Claims 1-10 are canceled. Claims 11-16 are pending. Claims 14-16 are withdrawn as being directed to a non-elected invention.

Response to Amendment

 The Affidavits filed on 05/10/2010 under 37 CFR 1.131 is sufficient to overcome the compound 10 of Blaakmeer's reference. The Declaration demonstrates that compound 108 Having this structure:

Which falls within the subgenus of compound 4 of the instant specification

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shows a 20 more fold higher ability of inhibiting all 3 selectins (E-, S-, and L-) than the compound D2-10 which corresponds to compound 10 of the prior art with this structure.

$$R_1$$
 R_2
 R_4
 R_6
 R_7

where R1, R2, R3 contain OH groups; R4 is –CH2.—CH2; R5 is OH; R7 is H and R6 and R8 are OH. Although the Declaration was sufficient to overcome the rejection based on compound 108 (a specie of compound 4), the results for compound 108 are not commensurate in scope with all the compounds of the instant claim 11. As such, compound 4 appears to be free of the art. Examination is expanded to the broad claim 11 where

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X' is

Response to Arguments

3. Applicant's arguments, filed 05/10/2010, with respect to the rejection Under 35 USC § 103 have been fully considered and are persuasive. The rejection of claims 11, 12, 14-16 has been withdrawn due to declaration presented by Applicant that demonstrates the present compound 108 exhibits a more than 20 fold higher activity to all three (E, P and L)-selectins than the compound 10 of Blaakmeer. Rejections and objections not reiterated form previous Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

New Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaakmeer et al. (Structure-Activity relationship of isolated avenanthramide alkaloids and synthesized related compounds as oviposition deterrents for Pieris Brassicae, Journal Of Natural Products, Vol. 57, No. 8, pp. 1145-1151, August 1994) previously cited in view of.

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Patani et al. (Bioisosterism: A Rational Approach in Drug Design, Chemical Rev., 1996, 96

(8), 3147-3176) previously cited

The instant application is drawn to a pharmaceutical composition comprising at least one of the formula C or D and a pharmaceutically acceptable carrier which is useful in a medicine.

Y' is

-(HN)s-, R8 and R9a can be at any position on the ring, except where R7 and W-R6 is already attached.

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Blaakmeer teaches structure-activity relationship investigation of several compound isolated from the eggs of Pieris brassicae, large cabbage butterfly and eight synthesized related compounds as oviposition deterrents for the insect where their activities were tested in a dual-choice bioassay. The specie compound 5, trans-2-[3-(3,4,5-trihydroxyphenylpropenoyl)amino]-3,5-dihydroxybenzoic acid methyl ester (Abstract and page 1146).

This compound reads on the compound of claim 11 outlined above where W=(CH2)v and v=0; R7 is H; R8=R6-OCH3; R9a=CH3. The bioassay of Blaakmeer is an indication that the compound can be in used in a pharmaceutical composition.

Blaakmeer does not teach an OH group for R9a and a pharmaceutically acceptable carrier.

Patani teaches hydroxyl and methyl groups are bioisostere via Grimm's hydride displacement law (page 3148, table 9).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to interchange an hydroxyl group for a methyl group as suggested by Patini. Bioisosteres are compounds that differ by an atom or radicals that share similar physiochemical properties and consequently two compounds that are bioisosteres of one another have similar biological activity. Accordingly, the compounds are deemed unpatentable therefrom

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in the absence of a showing of unexpected results for the claimed invention over the prior art compound.

It would have been obvious as well to formulate a pharmaceutical composition to include a pharmaceutical acceptable carrier system such as solvents, and other conventionally known adjuvants since it is well know in the art when making a pharmaceutical composition to include a carrier for drug delivery and since Blaakmeer suggests that the compound can be used as pharmaceutical active compound by testing the compound for bioassay. The technique and skill for adding and selecting a carious materials are well within the level of the ordinary skilled artisan and commonly practiced in the state of the art and thus, obvious absent evidence to the contrary.

Claims 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Blaakmeer* et al. (Structure-Activity relationship of isolated avenanthramide alkaloids and synthesized related compounds as oviposition deterrents for Pieris Brassicae, Journal Of Natural Products, Vol. 57, No. 8, pp. 1145-1151, August 1994) previously cited in view of *Patani et al.* (Bioisosterism: A Rational Approach in Drug Design, Chemical Rev., 1996, 96 (8), 3147-3176) previously cited as applied to claims 11 and 12.

The teachings of Blaackmeer and Patani et al have been outlined supra.

However the difference between Blaakmeer in view of Patani et al and the instant formula (D) is the position of the following group on the ring.

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The structure below is Formula D

In the instant application, the position of the acryloylamino is on the first carbon of the phenyl ring. In the prior art compound the acryloylamino is on the sixth carbon of the phenyl ring. The prior art compound and the instant compound are positional isomers of one another. A positional isomer is a set of structural isomers which differ by only in the point at which a side chain group is attached. Position isomers have similar chemical properties since they differ only in the location of the functional group.

Since positional isomers have similar chemical properties, and since they differ only in the location of the functional group, it would have been obvious to one of ordinary skill in the art to synthesize positional isomers of the class of compounds. Accordingly, the compounds and compositions are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compound over the prior art compound.

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Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1988); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPO 644 (CCPA 1962).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January I, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3,73(b).

. Claims 11-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-6 of copending Application No.

12/067,0598. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both the instant and copending applications are drawn to a composition comprising a triply hydroxylated phenyl ring core. The variable subgroups of both the instant and the copending applications overlap. The compounds of the instant and copending applications are positional isomers and are, thus, considered obvious variants of each other. "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by –CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds

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possess similar properties." *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers *primafacie* obvious). (MPEP § 2144.09(II))

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEAN CORNET whose telephone number is (571)270-7669. The examiner can normally be reached on Monday-Thursday 7.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/JC/

/Brandon J Fetterolf/ Primary Examiner, Art Unit 1642